

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

DMB

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Certifier	<i>[Signature]</i>

**Ophthalmic and Topical Dosage Form New Animal Drugs; Change of Sponsor**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Dow B. Hickam, Inc., to Bertek Pharmaceuticals, Inc.

**DATES:** This rule is effective *[insert date of publication in the Federal Register]*.

**FOR FURTHER INFORMATION CONTACT:** Norman J. Turner, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0214.

**SUPPLEMENTARY INFORMATION:** Dow B. Hickam, Inc., Pharmaceuticals, P.O. Box 35413, Houston, TX 77035, has informed FDA that it has transferred to Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478, ownership of, and all rights and interests in NADA 39-583. Accordingly, the agency is amending the regulations in 21 CFR 524.2620 to reflect the transfer of ownership.

In addition, Bertek Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c)(1) and (c)(2) is being amended to add entries for the firm.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

## List of Subjects

### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

### 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 524 are amended as follows:

## PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for “Dow B. Hickam, Inc.” and by alphabetically adding an entry for “Bertek Pharmaceuticals, Inc.” and in the table in paragraph (c)(2) by removing the entry for “000514” and by numerically adding an entry for “062794” to read as follows:

**§ 510.600**      **Names, addresses, and drug labeler codes of sponsors of approved applications.**

\*      \*      \*      \*      \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478	062794

(2) \* \* \*

Drug labeler code	Firm name and address
062794	Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478

## PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

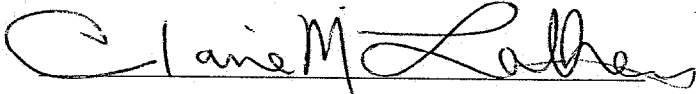
§ 524.2620 [Amended]

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4 <sup>2</sup> Section 524.2620 *Liquid crystalline trypsin, Peru balsam, castor oil* is amended in paragraph (a)(2) by removing "000514" and adding in its place "062794".

Dated: 8/23/01

August 23, 2001.



Claire M. Lathers,  
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Office of New Animal Drug Evaluation,  
Center for Veterinary Medicine.

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